REMARKS

Claim Status

Claims 1, 2, and 5 are amended presently. No new matter has been added. Upon entry of this amendment, claims 1-28 will be pending and elected claims 1-7 and 18-27 will be presented for examination.

In the Specification

The disclosure is objected to because "it contains an embedded hyperlink and/or other form of browser-executable code." Office Action, item 3, page 3. Applicants removed the browser-executable code and believe the specification complies with MPEP § 608.01.

Claim Objections

Claim 1 is objected to because it contain non-elected sequences. Office Action, item 4, page 3. The present version of claim 1 moots this objection.

Rejections under 35 U.S.C. § 112 (Indefiniteness)

Claims 2-3, 5, and 7 are rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Office Action, item 5, page 4.

Claim 2 is rejected because "the recitation 'does not normally regulate' renders the claim indefinite." *Id.* The PTO suggests replacing this language with "is heterologous to." *Id.* Per the PTO's suggestion, present claim 2 clarifies that the promoter is heterologous to an operably linked coding sequence. Accordingly, Applicants respectfully request the rejection's withdrawal.

Claim 5 is rejected for alleged lack of antecedent basis. *Id.* Currently amended claim 5 corrects a typographical error, thus obviating the rejection.

Rejections under 35 U.S.C. § 112 (Written Description)

Claims 1-7 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, for alleged lack of written description. Office Action, item 6, pages 4-6. As an initial matter, the PTO takes the position "the claims are broadly drawn to a genus of sequences that hybridize under stringent conditions to '**a** nucleotide sequence set forth in SEQ ID NO: 2'...." *Id.* at page 5 (emphasis in original). Based on the PTO's interpretation "'**a** nucleotide sequence set forth in SEQ ID NO: 2' encompasses any dinucleotide sequence in SEQ ID NO: 2 and that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity." *Id.* (emphasis in original).

While Applicants do not agree with the PTO's interpretation that SEQ ID NO: 2 inherently contemplates an indefinite number of sequences, such as dinucleotide sequences, particularly when the MPEP requires assignment of separate sequence identifiers for all disclosed sequences, the present claims avoid the PTO's concerns by reciting "**the** nucleotide sequence set forth in SEQ ID NO: 2."

Additionally, the PTO alleges "the specification does not describe the structure of any other species in the claimed genus except for SEQ ID NO: 2 itself. Neither the specification nor the prior art teaches conserved structures that are essential for promoter activity." *Id.* at page 6. Applicants respectfully traverse the grounds for this rejection.

According to the MPEP, the PTO has the initial burden of presenting evidence why a person skilled in the art would not recognize in Applicants' disclosure a description of the invention defined by the claims. *See* MPEP § 2163. While the PTO admits that Applicants disclose structural features of the recited sequence (i.e. SEQ ID NO: 2), the PTO does not provide any evidence explaining why the ordinarily skilled artisan would not understand the metes and bounds of the invention as claimed. Thus, the PTO bases its rejection on the grounds that Applicants allegedly have not described "conserved structures that are essential for promoter activity." *Id.*

Contrary to the PTO's stated position, however, the present specification necessarily discloses structural features common to members of the claimed genus of polynucleotides.

As the PTO admits, the specification discloses SEQ ID NO:: 2 itself, which is indisputably central and common to the claimed genus. Thus informed by the structural underpinnings of SEQ ID NO: 2, the skilled person would understand that sequences having 65% identity with SEQ ID NO: 2, wherein said sequences have promoter activity. The specification itself describes such a genus of polynucleotides in published paragraph numbers [0036] and [0037], which relate "such variants and/or fragments may retain the biological activity and therefore drive, in a cambium/xylem preferred manner, the expression of operably linked nucleotide sequences." *See* published paragraph number [0036]. Furthermore, and again in apt with the PTO's stated position, the present specification does indeed correlate structure with function. Specifically, the specification discloses "a promoter generally comprises specific signaling sequences called boxes, arranged along the promoter sequence, such that its composition determines the temporal and spatial expression of a gene that is under its regulatory control." *See* published paragraph number [0019]. Here, the disclosed promoters confer cambium/xylem-preferred expression.

Informed by both structure and function, the skilled person would be able to identify which nucleotides in a defined region of SEQ ID NO: 2 could withstand modification/variation and yet still produce a functional promoter sequence having the recited percentage sequence identity with SEQ ID NO: 2. This is so because sequence software programs, such as the BLAST suite, are publicly available, intended for this very purpose, and referenced in the specification. *See*, e.g., published paragraph number [0049].

According to the PTO's own "Guidelines for Written Description," an Examiner must consider identifying characteristics of an inventive nucleotide or amino acid sequence, such as disclosure of partial structure, functional characteristics, known or disclosed correlation between structure and function, and physical and/or chemical properties. Disclosure of any of these characteristics, or combination thereof, sufficiently meet the requirements for written description. *See* Guidelines for Written Description, page 10 (copy submitted herewith). Because Applicants disclose both structure and function, from this consideration alone, the instant claims surely satisfy Section 112 written description.

Moreover, Example 11A of the application provides written description for "percent identity" claims. *See* Guidelines for Written Description, pages 46-51. That is, Example 11A provides an illustrative claim reciting an "isolated nucleic acid sequence that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2." *Id.* at page 46. Notably, the specification discloses only a single species (SEQ ID NO: 1) that encodes SEQ ID NO: 2 and the specification does not provide any drawings or structural formulae that encode SEQ ID NO: 2 or a sequence with 85% identity to SEQ ID NO: 2. *Id.* at page 48. In analyzing whether the illustrative claim complies with the written description requirement, the PTO states (1) the genetic code and its redundancies were known in the art before the application was filed and (2) with the aid of a computer, one of skill in the art could have identified all the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2. *Id.* at pages 50-51. Accordingly, the PTO concludes that Applicant was in possession of the claimed genus at the time of filing and that the specification satisfies the requirements of Section 112, first paragraph.

Based on the specification's own disclosure, as well as the PTO's treatment of percent identity claims as iterated in the "Guidelines for Written Description," it is beyond dispute that the specification provides written support for claims 1-7 and 18-27, rendering the present rejection improper and subject to withdrawal.

Rejections under 35 U.S.C. § 112 (Enablement)

Claims 1-7 and 18-27 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Office Action, item 7, pages 6-9. While acknowledging that the specification enables SEQ ID NO: 2 and fragments thereof having cambium/xylem preferred promoter activity in plants and bacteria, the PTO alleges that the specification "does not reasonably provide enablement for any other variants of SEQ ID NO: 2 having cambium/xylem preferred promoter activity or transgenic host cell other than plants and bacteria." *Id.* at page 6. The PTO bases its rejection on its interpretation of "**a** nucleotide sequence set forth in SEQ ID NO: 2" *Id.* at page 7 (emphasis in original).

Further, the PTO cites Fourgoux-Nicol *et al.*, *Plant Molecular Biology* 40: 857-72 (1999), as allegedly teaching "isolating DNA fragments using stringent hybridization conditions does not always select for DNA fragments whose contiguous nucleotide sequences is the same or nearly the same as the probe." *Id.* at page 8. Based on the disclosure of Fourgoux-Nicol *et al.*, the PTO alleges "undue experimentation would be required by one skilled in the art to make and use the claimed invention with DNA that has at least 50% sequence identity to the nucleotide sequence of SEQ ID NO: 2." *Id.* at page 9. Applicants respectfully traverse the grounds for this rejection.

At the outset, and as discussed above for "Written Description," Applicants do not agree with the PTO's interpretation that SEQ ID NO: 2 inherently contemplates an indefinite number of sequences. However, in an effort to advance prosecution, the present claims recite "**the** nucleotide sequence set forth in SEQ ID NO: 2."

More substantively, and contrary to the PTO's position, neither the Patent Statute nor the MPEP requires Applicants to provide examples for every embodiment disclosed. Furthermore, the Federal Circuit has made it quite clear that absent a clear disclaimer of particular subject matter, claims should not be narrowed to reflect only those embodiments disclosed in the examples. "We have repeatedly held that, even in situations when only one embodiment is disclosed, the claims generally should not be narrowed to cover only the disclosed embodiments or examples in the specification." *Linear Technology Corp. v. Int'l Trade Comm'n,* 566 F.3d 1049 (Fed. Cir. 2009).

In addition to the specification's own disclosure, the state of the art at the time of filing was advanced such that an ordinarily skilled artisan would be able to identify which nucleotides in SEQ ID NO: 2 could withstand modification/variation and yet still produce a functional promoter sequence having the recited percentage sequence identity with SEQ ID NO: 2. This is so because sequence software programs, such as the BLAST suite, are publicly available, intended for this very purpose, and referenced in the specification. *See*, e.g., published paragraph number [0049].

In fact, the PTO's own reference, Fourgoux-Nicol *et al.*, discloses a promoter sequence, and importantly, the authors determined using various sequencing programs known in the art that their promoter sequence contains regions/motifs identified previously in similar plant promoters. Specifically, Fourgoux-Nicol *et al.* discloses a male gametophyte-specific promoter denoted *BnM3.4* that shares structural features with other male gametophyte-specific promoters. *See* Fourgoux-Nicol *et al.*, Abstract. Thus, the PTO's own reference provides proof positive that the ordinarily skilled artisan could determine which nucleotides in SEQ ID NO: 2 could withstand modification/variation and yet still confer promoter activity.

Accordingly, in view of the specification's own disclosure of how to practice the claimed invention, as well as the advanced state of the art at the time of Applicants' filing, claims 29-38 and 43-46 are supported by an enabling disclosure.

Rejections under 35 U.S.C. § 102

Claims 1-7 and 18-27 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Xue *et al.* (2002). Office Action, item 8, page 10. Specifically, the PTO alleges "Xue *et al.* teach that 4CL promoter is highly specific for xylem expression in tobacco. Given that '**a** nucleotide sequence set forth in SEQ ID NO: 2' encompasses any dinucleotide sequence in SEQ ID NO: 2 and that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity." *Id.* Applicants respectfully traverse the grounds for this rejection.

In order to anticipate, a reference must disclose each and every element of the claim. MPEP § 2131. Because Xue *et al.* does not disclose the nucleotide sequence set forth in SEQ ID NO: 2, this reference could not anticipate the claimed invention. Accordingly, the rejection is improper and should be withdrawn.

CONCLUSION

Applicants submit the claims are in condition for allowance.

If there are any questions concerning this application, the Examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

Date 15 February 2010 By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extension is needed for timely acceptance of submitted papers, Applicants petition for such extension under 37 CFR §1.136 and authorize payment of the relevant extension fee(s) from the deposit account.

Written Description –Basics of Examiner's Analysis (cont.)

c. Sufficient relevant identifying characteristics:

   i. Complete structure

   ii. Partial structure

   iii. Physical and/or chemical properties

   iv. Functional characteristics when coupled with correlation between structure and function

Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613; MPEP 2163

Example 11A- Percent Identity

- Claims:
  - Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.
  - Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a SEQ ID NO: 2; wherein the polypeptide has activity X.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - Claim 1 encompasses nucleic acids
    - that encode the polypeptide of SEQ ID NO: 2
    - that encode any polypeptide having 85% structural identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - Actual reduction of only a single species that encodes SEQ ID NO: 2; i.e., SEQ ID NO: 1.
  - No other drawings or structural formulas disclosed that encode either SEQ ID NO: 2 or a sequence with 85% identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - The recitation of a polypeptide with at least 85% identity represents a partial structure.
    - Up to 15% of the amino acids may vary from those in SEQ ID NO: 2.
    - No information about which 15% may vary from SEQ ID NO: 2.
  - There is no functional limitation on the nucleic acids of claim 1 other than they encode the polypeptide of SEQ ID NO: 2 or any polypeptide having 85% structural identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - The genetic code and its redundancies were known in the art before the application was filed.

Example 11A- Percent Identity

- Conclusion (Claim 1):
  - SEQ ID NO: 2 combined with the genetic code would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2.
  - With the aid of a computer, one of skill in the art could have identified all the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2.
  - One of skill in the art would conclude that applicant was in possession of the claimed genus at the time of filing and the specification satisfied the requirements of 35 U.S.C. 112 first paragraph.

**This example deals only with the written description analysis. Enablement issues that may be raised are not addressed.*